Premarket Notification Summary, K092398

Manufacturer and Submitter

Cryo Bio System
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FRANCE

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OCT 6 2010

Date Prepared: 17 September 2010

Establishment Registration

Cryo Bio System
Owner Operator Number: 9042657

Device Trade Name

HSV Straw

Device Generic Name

Cryopreservation straw

Device Classification and Product Code

Class II (Special Controls) per Final Rule, 63FR 48428, Docket number 97N-0335
21 CFR 884, Subpart G, 884.6160 Assisted Reproduction Labware

Product Code: MQK

Indications for Use

The HSV Straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 Cell and blastocyst stage embryos.

Device Description and Principles of Operation for the HSV Straw

An embryo is vitrified using the HSV Straw by placing an embryo suspended in a 0.5ul drop of the final vitrification solution in a curved polymeric spatula (Medical Grade. Styrene-Butadiene Copolymer). The curved spatula is inserted in an outer straw with a sealed, weighted distal end. The open, proximal end of the straw is sealed by the user. The sealed straw is placed in liquid nitrogen to effect freezing-vitrification. The weighted straw remains immersed in liquid nitrogen for embryo storage. Thawing-rewarming: While the distal tip remains in liquid nitrogen, part of the outer tube is cut away. The curved spatula, containing the cryopreserved embryo, is removed from the outer straw and immediately immersed in thawing solution where thawing and dilution of the remaining vitrification solution occur simultaneously.

Technological Characteristics of the HSV Straw Compared to Predicate Devices

Attribute	HSV Straw™, CryoBio System	Curently marketed, previously FDA cleared, cryopreservation device. CryoTip™, Irvine Scientific, Irvine CA	Curently marketed, previously FDA cleared, cryopreservation device. Rapid-i™, Vitrolife Sweden AB, Gothenberg, Sweden
510(k) #	K092398	K041562	K090832
Indications for use	The HSV Straw is a cryopreservation device designed to contain, vitrify and maintain 4-8 cell and blastocyst stage human embryos.	The Cryotip™ is a cryopreservation device that is intended to be used to contain, freeze and maintain oocytes and/or embryos.	Rapid-i™ is a cryopreservation device indicated to be used to contain, vitrify and maintain 4-8 cell stage embryos.
Method of action (vitrification)	An embryo, suspended in a 0.5ul drops of the final vitrification solution, is placed in the curved spatula. The curved spatula is inserted in the outer straw and the open end of the straw sealed. The sealed straw is placed in liquid nitrogen.	Embryo samples suspended in the final vitrification solution are aspirated into a capillary tube and seals are effected on each side of the sample. Subsequently, the tube is immersed in liquid nitrogen.	Prefreeze a straw with the open end extending from the liquid nitrogen. A 10 nanoliter drop of vitrification solution holding an embryo is placed in a capillary sized through hole in the stick. This, in turn, is inserted in the pre frozen straw in liquid nitrogen to effect freezing of the embryo. Subsequently, the open end of the straw is sealed.
Cooling Rate[1]. See note	2,900°C/min	12,000°C/min	1,220°C/min
Method of action (rewarming)	While the distal tip of the outer tube remains in liquid nitrogen, part of the outer tube is cut away. The curved spatula, containing the cryopreserved embryo, is immersed in thawing solution where thawing and dilution in the thawing solution occur simultaneously.	The capillary tube with sample is removed from liquid nitrogen and placed in a temperature controlled solution. After thawing, the tube is cut open and the embryo and vitrification solution are washed out into a dilution solution.	While the distal end of the straw remains in liquid nitrogen, cut the sealed proximal end of the straw. Withdraw the stick and directly immerse the stick/vitrified drop in warming media.
Rewarming Rate[1]. See note	25,000°C/min	41,098°C/min	7,700°C/min
Materials in contact with tissue (embryos)	Medical Grade Styrene-Butadiene Copolymer.	Medical grade polyvinyl chloride straw.	Polymethyl methacrylate (PMMA) stick and a poly vinyl chloride (PVC) straw.
Warming: Contact with the warming medium	Direct immersion of sample in the warming solution for simultaneous thawing and dilution.	The sealed straw is first immersed in solution and warmed/thawed. In a second step, the thawed sample is expelled and diluted in the warming solution.	Direct immersion of sample in the warming solution for simultaneous thawing and dilution.

Note: The cooling/heating performance of the CryoTip and HSV devices were determined by laboratory testing with microminature temperature monitoring. Data for the Rapid-I device was interpolated from the publication: Tarankonov et al, 2009, Numerical Simulations Demonstrate Safe Vitrification and Warming Embryos Using the Rapid-i™ Device, *Proceedings of the COMSOL Conference 2009, Milan.*

Substantial Equivalence to Marketed Products

Predicate devices:

Cryotip, Irvine Scientific, Irvine CA, K041562

Rapid-i, Virtrolife Sweden AB, K090832

Clinical use of the HSV Straw was studied in three centers representing diverse approaches to assisted fertility (blastomeres vs blastocysts, multiple embryo transfers vs single embryo transfers, hormone induced cycles vs natural cycles, etc). A total of 473 vitrification cycles using 1509 embryos were captured in the study. Each of the three centers had post vitrification/rewarming embryo % survival of greater than 80%. No device associated adverse effects were experienced by the study sites and the centers continue to routinely use the device. The three centers had high levels of embryo survival after thawing and successfully used the vitrified embryos for pregnancies and live births.

The submission contains information demonstrating substantial equivalence between the devices. Test data in the submission include mouse embryo assay (MEA), endotoxin and sterility data, mechanical testing, and heating and cooling rate data. MEA testing with mouse blastocysts at 96 hours yielded 90-100% survival and endotoxin testing consistently demonstrated <1 EU per unit. Mechanical testing demonstrated the performance of the device under use conditions.

Design information included in the submission demonstrated that the curved form of the spatula, surface tension of the embryo containing drop and device dimensions and configuration provide a safe environment whereby the embryos are protected from nitrogen contamination inside a sealed straw.

When the HSV Straw is used in accordance with indications and instructions for use, the differences between the HSV Straw and predicate devices do not raise new questions of safety and effectiveness. The clinical studies of the HSV Straw and engineering and other tests did not identify any adverse effects. This conclusion is based on the performance data and specifications. It can be concluded that the intended use, material composition and scientific technology properties of the HSV Straw demonstrate that the device is as safe, as effective, and performs as well as or better than the identified, legally marketed predicate devices in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Cryo Bio System
% Mr. David Balding
Consultant
26552 Tampico Place
MISSION VIEJO CA 92691

OCT 6 2010

Re: K092398
Trade Name: HSV Straw
Regulation Number: 21 CFR §884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: September 17, 2010
Received: September 21, 2010

Dear Mr. Balding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092398

Device Name: HSV Straw

Indications for Use: The HSV Straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 Cell and blastocyst stage embryos.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K092398